

Press  
Release

# Vifor Pharma Group reports strong growth in 2019, exceeding raised guidance

- Net sales and EBITDA exceeded raised full-year guidance as a result of continued execution of the three strategic growth drivers
- Etienne Jornod to step down as Executive Chairman. Jacques Theurillat proposed to be elected as new Chairman
- Stefan Schulze appointed CEO Vifor Pharma Group
- Ferinject® / Injectafer®: Blockbuster status achieved one year earlier than anticipated
- Nephrology portfolio driven by strong US performance of Velphoro® and Mircera®
- Veltassa® delivered significant growth in the US by expanding the hyperkalaemia market

**ST GALLEN, 12 MARCH 2020** – Vifor Pharma Group recorded strong financial and operational performance in 2019 by focusing on its three strategic growth drivers while continuing to invest in its pipeline. The company exceeded its raised guidance for full-year 2019 on both net sales and EBITDA.

## FINANCIAL PERFORMANCE: STRONG SALES AND PROFIT GROWTH CONTINUES

- Net sales of CHF 1,877.2 million, up 18.5%
- EBITDA of CHF 540.0 million, up 37.9%
- Core EPS of CHF 4.67
- Strong balance sheet with equity ratio of 75.7%
- Net cash position of CHF 5.7 million
- Investment grade credit rating from Standard & Poor's received in September 2019 and from Fitch Ratings in March 2020
- Initiation of the sale process for OM Pharma

## FERINJECT® / INJECTAFER® ACHIEVES BLOCKBUSTER STATUS

- In-market sales of CHF 1.06 billion, up 19.1% from the previous year reinforcing status as the world leading i.v. iron therapy
- Net sales increased 15.6% to CHF 561.0 million, by 17.5% in local currency
- Strong performance mostly driven by the US market (+18.7%)
- Growth of 20.1% adjusting for inventory impacts and increased demand due to INFeD shortages in 2018
- Strategic partnership with Fresenius Kabi China announced in February 2020

## EXPANSION OF NEPHROLOGY PORTFOLIO CONTINUES

- Mircera® net sales CHF 523.4 million, up 16.0%, due to continued expansion in mid-sized organisation dialysis clinics in US
- Velphoro® net sales CHF 181.7 million, up 89.9%, driven by strong US growth from continued adoption of updated KDIGO guidelines
- Venofer® net sales CHF 132.4 million, up 12.0%, mostly driven by strong US demand
- Positive top-line data from pivotal phase-III ADVOCATE trial announced in November 2019 demonstrating avacopan's superiority over standard of care at week 52 in ANCA-associated vasculitis

## **VELTASSA® CONTINUES TO DRIVE GROWTH OF HYPERKALAEMIA MARKET**

- Net sales CHF 132.3 million, up 46.2%, with US net sales of CHF 124.8 million
- Roll out continued in Europe with additional launches in Spain, Austria, Belgium and The Netherlands
- Reimbursement secured in Germany, Austria, Belgium, Finland, Portugal and Spain
- Positive recommendation for funding received from NICE in the UK in December 2019
- Positive results from AMBER study demonstrating potential in renin-angiotensin-aldosterone inhibitor medication (RAASi) enablement with Veltassa® in patients with resistant hypertension and CKD
- Global phase-IIIb outcome study DIAMOND initiated to evaluate the potential of Veltassa® in combination with RAASi to improve patient outcomes reducing cardiovascular mortality and hospitalisations

## **CONTINUED FOCUS ON BUSINESS DEVELOPMENT & PIPELINE TO DELIVER GLOBAL LEADERSHIP IN IRON DEFICIENCY, NEPHROLOGY AND CARDIO-RENAL THERAPIES**

- Collaboration with Janssen Pharmaceuticals Inc. to commercialise Invokana® in US to nephrologists for patients with diabetic kidney disease
- Partnership with Evotec, by creating a 50:50 joint venture, NephThera, to discover and develop novel nephrology therapeutics
- Orphan drug designation granted by FDA and EMA to VIT-2763 (ferroportin inhibitor) for treatment of beta-thalassemia; phase-II study activities initiated in Q4 2019

## **ENSURING CONTINUED COMMERCIAL SUCCESS WITH THE RIGHT PEOPLE**

- Appointment of Dr Klaus Henning Jensen as Chief Medical Officer and member of the Executive Committee with effect from January 2020
- Appointment of Lee Heeson as President International and member of the Executive Committee with effect from February 2020

Commenting on the 2019 results, Etienne Jornod, Executive Chairman of Vifor Pharma Group, said:

*"Vifor Pharma Group recorded another excellent performance in 2019, focusing relentlessly on delivery and execution of our strategy. We continued to maximise our current products and future pipeline, while carefully managing costs and ensuring positive returns for our shareholders. Once again, we have kept our promise to shareholders, delivering strong, profitable growth and exceeding our raised 2019 guidance. A strong focus on execution has enabled us to continue to build on our three strategic growth drivers. We remain on track to meet the ambitious Milestone 2020 targets which we set ourselves in 2017."*

## **ETIENNE JORNOD TO STEP DOWN AS EXECUTIVE CHAIRMAN, STEFAN SCHULZE APPOINTED CEO**

After 25 years of service the Executive Chairman of the Board of Directors of Vifor Pharma, **Etienne Jornod**, has decided not to renew his mandate, which expires at the Annual General Meeting of May 14, 2020.

**Stefan Schulze**, currently President of the Executive Committee and Chief Operating Officer (COO) is appointed CEO for Vifor Pharma Group as of May 14, 2020.

"At the request of major shareholders, I decided to accompany the first phase of Vifor Pharma's entrepreneurial independence when Galenica and Vifor Pharma were split up in 2017 and to run the plan "Milestone 2020", says **Etienne Jornod**. "Today, with all objectives of such plan being overachieved Vifor Pharma is established as a stand-alone pharmaceutical company and has made outstanding progress. I have come to the end of my mandate and I believe this is the perfect time to hand over the responsibility to my successors to lead the Group. Vifor Pharma is today on the right track, with a renewed, strong and experienced BOD and EC members, all projects on track. Vifor Pharma has excellent prospects with many new products to be launched in the next years. The company's Board of Directors has been almost completely renewed since the IPO of Galenica Sante over the last 3 years, with the addition of significant international and pharma expertise. The Executive Committee has also been

reinforced with 3 very experienced international executives. Stefan Schulze has successfully established and led the Executive Committee and executed on the strategy since 2017 and the Executive Committee has proven that it has the competence and experience to address the challenges and opportunities of the company going forward".

**Stefan Schulze**, an engineer by education, spent his professional career in the healthcare industry in the U.S. and Europe. He was working for the Fresenius Group in various positions from 1992 to 2014. In 2014 he became CEO of Vifor Fresenius Medical Care Renal Pharma – a joint company of Vifor Pharma and Fresenius Medical Care. Stefan is COO and President of the Executive Committee of the Vifor Pharma Group since 2017.

The Board of Directors proposes **Jacques Theurillat** to be elected by the shareholders as the new Chairman of the Board of Directors. All other Board members will stand for re-election. **Gilbert Achermann**, currently Chairman of the Board of Straumann Group, is proposed to become member of the Board to succeed **Jacques Theurillat** in the ARC (Audit and Risk Committee).

**Jacques Theurillat** has an extensive experience in the pharmaceutical and healthcare industry. From 1987 to 2006, he held various positions at Serono, including CFO and Deputy CEO. He was a member of the Board of Directors of Serono since 2000 until the sale of the company in 2006. He has served in thirteen different Boards during his career and at present, he is a founding partner of Sofinnova Crossover 1 Fund in Paris and a member of the Boards of CNH Industrials N.V., Mundipharma Ltd and ADC Therapeutics SA. Jacques Theurillat is a Swiss attorney-at-law and Swiss chartered tax expert and was elected to the BoD of Vifor Pharma in 2018.

**Jacques Theurillat** comments: "The Board of Directors and I would like to sincerely thank Etienne Jornod for his excellent achievements in the past 25 years. Under his leadership and tenure the group has grown steadily from a value of 230 million Swiss francs to two listed companies with a total value of around 3 billion and 11 billion Swiss francs respectively, and today employ approximately 10,000 people. It has been a tremendous honor to work with him for all of us"

**Etienne Jornod** has spent his entire professional life to date with the Vifor Pharma Group (formerly Galenica until it changed its name to Vifor Pharma in 2017). Joining the company in 1975 as Junior Product Manager he was appointed to the Corporate Executive Committee in 1988. In 1995 he was appointed COO of the Galenica Group and a few months later he was appointed Chairman and CEO. **Etienne Jornod** has also been appointed Honorary Chairman of Galenica in 2017 as well as Honorary Chairman of Vifor Pharma in 2020. He will act as advisor and counsel to his successors, the Non-Executive Chairman and the CEO of Vifor Pharma Group.

"It is fantastic to be involved in the leadership and renewal of first-class management teams and employees," says **Etienne Jornod**. "Devoting my life to Vifor Pharma and Galenica would never have been possible without the unconditional support of my wife and children. I am grateful to all those who have enabled me to live my passion". "For the last 5 years, because of the takeover of Relypsa, the IPO of Galenica Santé and the launch of Vifor Pharma, I had almost no time for vacation, I will compensate this now, that is for sure!"

## 1. FINANCIAL PERFORMANCE

<i>In million CHF</i>	<i>FY 2019</i>	<i>FY 2018</i>	<i>Change in %</i>
<b>Net sales</b>	1,877.2	1,584.6	18.5%
<b>EBITDA</b>	540.0	391.5	37.9%
<b>Net profit after minorities</b>	159.1	152.4	4.4%
<b>Core earnings per share (in CHF)</b>	4.67	4.16	12.2%

For further details, please see the Vifor Pharma Group 2019 Report (PDF) at [www.viforpharma.com](http://www.viforpharma.com).

## KEY PROFIT AND LOSS FIGURES

Vifor Pharma Group **net sales** grew to CHF 1,877.2 million, a strong increase of 18.5% compared to the previous year or of 18.4% in local currency. **EBITDA** increased to CHF 540.0 million compared to CHF 391.5 million in the previous year, or +37.9%.

The Group made changes to its defined benefit pension plan (IAS 19) in 2019 which resulted in a positive impact to EBITDA of CHF 27.2 million. Excluding this IAS 19 impact, EBITDA grew to CHF 512.8 million or by 31.0%.

**Other income** declined to CHF 38.4 million from CHF 64.6 million in 2018. This was primarily due to the expected decrease of royalty payments from CellCept® due to the sunset clause as well as lower income from partnering activities.

**Cost of sales** amounted to CHF 761.5 million compared to CHF 648.7 million in the previous year, resulting in a **gross profit margin** of 60.3% compared to 60.7% in the prior period. This slight decrease was primarily due to the decline in other income.

**Marketing and distribution expenses** amounted to CHF 455.3 million compared to CHF 410.8 million in the previous year. The main drivers were the investments in pre-launch activities of our pipeline products and the continued rollout of Veltassa®.

**Investments in research and development** amounted to CHF 228.3 million compared to CHF 206.4 million in the previous year. The increase was driven by the DIAMOND study for Veltassa®.

**General and administration expenses** amounted to CHF 145.7 million compared to CHF 155.9 million in the previous year. The decrease is mainly attributable to cost containment and the exceptional income resulting from the previously mentioned changes to the defined benefit pension plan (IAS 19).

**Core earnings per share** amounted to CHF 4.67, an increase of 12.2% compared to CHF 4.16 in 2018. Excluding the exceptional FX gain in the previous year and the positive impact from IAS 19 in the current year, core earnings per share increased by 23.2%. Core earnings are defined as reported earnings after minorities adjusted for proportionate amortisation of intangible assets of CHF 143.9 million in 2019 (2018: CHF 117.5 million).

## CASH FLOWS

**As a result of the strong operating cash flow, Vifor Pharma Group achieved a net cash position of CHF 5.7 million at the end of 2019 compared to a net debt position of CHF 179.7 million at the end of 2018**

**Cash flow from operating activities** amounted to CHF +524.8 million compared to CHF +193.8 million in the previous year. The increase is due to the strong operating result of Vifor Pharma in 2019 as well as an optimised net working capital.

**Cash flow from investing activities** amounted to CHF -132.5 million mainly due to upfront and milestone payments for in-licensing agreements of CHF -88.2 million.

**Cash flow from financing activities** amounted to CHF -238.5 million and was mainly influenced by dividend distributions of CHF -174.7 million, whereof CHF -45.0 million was paid to Fresenius Medical Care and CHF -129.7 million was distributed to shareholders of Vifor Pharma.

## FINANCIAL POSITION

**Goodwill and intangible assets** amounted to CHF 2,584.5 million at the end of 2019 compared to CHF 2,676.0 million at the end of 2018, representing 52.4% of total assets (2018: 59.5%).

**Financial assets** amounted to CHF 510.3 million at the end of 2019 compared to CHF 208.2 million at the end of 2018. The increase is mainly due to the fair value gain on our equity investment in ChemoCentryx, Inc. following the successful result of the phase-III ADVOCATE trial in November 2019.

With CHF 3,735.3 million of **shareholders' equity**, Vifor Pharma Group had a strong equity ratio of 75.7% at the end of 2019 compared to 74.8% in 2018. The **return on equity after minorities** amounted to 5.0% in 2019, unchanged compared to 2018.

## 2. MAXIMISING THE POTENTIAL OF OUR STRATEGIC GROWTH DRIVERS

### Ferinject® / Injectafer®

Ferinject® / Injectafer® reinforced its position as the market-leading intravenous (i.v) iron therapy and achieved blockbuster status in 2019, one year earlier than anticipated.

Net sales of Ferinject®/Injectafer® increased by 15.6% to CHF 561.0 million, or by 17.5% in local currency. The global growth was driven by cardiology, gastroenterology and patient blood management. With significant market opportunity around the world, Ferinject®/Injectafer® reported net sales are expected to continue to grow in the high double-digit millions.

The latest available data showed global in-market sales of Ferinject®/Injectafer® of CHF 1.06 billion in 2019, up 19.1% from the previous year.

In the US, Injectafer® continued to drive i.v. iron market growth. Vifor Pharma's US partner American Regent, Inc., a Daiichi Sankyo Group company, recorded net sales of USD 444.8 million in 2019, an increase of 16.6%. This strong double-digit net sales growth occurred despite the positive impact in 2018 due to a US market shortage of a competitor product. In-market sales of Injectafer® in the US were CHF 502.4 million in 2019, up 20.0% from CHF 418.5 million in 2018. Growth continued in all key therapy areas, particularly gastroenterology, with in-market sales growth of 25% and patient blood management up 30%.

In March 2019, our partner in Japan, Zeria Pharmaceutical Co., Ltd. received marketing authorisation for Ferinject®, which is the first and only high dose i.v. iron approved in Japan. The product is expected to be launched in 2020 subject to successful reimbursement negotiations.

In February 2020, Vifor Pharma announced a strategic partnership with Fresenius Kabi China, part of the Fresenius Group, which is among the top 10 multinational pharmaceutical companies in China, specialising in infusion, transfusion and clinical nutrition.

### Nephrology

Net sales of the long-acting erythropoiesis-stimulating agent (ESA) Mircera® increased by 16.0% to CHF 523.4 million in 2019 from CHF 451.3 million. This was mainly due to continued expansion of sales in mid-sized organisation dialysis clinics in the US. Strong penetration has now been reached in both the Fresenius Kidney Care clinics, mid-sized and independent clinics in the US.

Net sales of the i.v. iron sucrose Venofer® increased to CHF 132.4 million in 2019, up 12.0% from CHF 118.2 million in 2018, of which the largest market remains the US. Global in-market sales for Venofer® amounted to CHF 475.5 million in 2019, up 7.8% from the previous year. Vifor Pharma combined market share of Ferinject® and Venofer® in value amounted to 72.1% of the i.v. iron market in 2019.

Net sales of Velporo<sup>®</sup> increased by 89.9% in 2019 to CHF 181.7 million, from CHF 95.7 million. Global in-market sales amounted to CHF 372.6 million. Strong growth was driven by the US, supported by the continued adoption of the updated Kidney Disease Improving Global Outcomes (KDIGO) guidelines.

In November 2019, the joint company Vifor Fresenius Medical Care Renal Pharma (VFMCRP) and its partner ChemoCentryx, Inc. announced positive top line data from the pivotal phase-III ADVOCATE trial of avacopan in 331 patients with ANCA-associated vasculitis. Both primary endpoints of clinical remission at weeks 26 and 52 achieved with statistical superiority of avacopan over standard of care at 52 weeks.

In November 2019, Vifor Pharma announced a partnership with Janssen Pharmaceuticals Inc. to commercialise Invokana<sup>®</sup> (canagliflozin) in the US to nephrologists to treat diabetic kidney disease (DKD) and reduce the risk of hospitalisation for heart failure in patients with type 2 diabetes and DKD.

Also in November, Vifor Pharma and Evotec SE created NephThera, a jointly-owned (50:50) drug discovery and development company for innovative nephrology therapeutics.

### **Veltassa<sup>®</sup>**

Veltassa<sup>®</sup> net sales of Veltassa<sup>®</sup> increased by 46.2% to CHF 132.3 million in 2019 from CHF 90.5 million. Net sales in the US amounted to CHF 124.8 million (USD 124.8 million), a 41.6% increase compared to 2018. Roll out continued in Europe with additional launches in Spain, Austria, Belgium and The Netherlands. Veltassa<sup>®</sup> has driven the expansion of the global potassium binder market from CHF 175.7 million in 2016 to CHF 340.4 million in 2019.

In Europe, Veltassa<sup>®</sup> has secured reimbursement in Germany, Austria, Belgium, Finland, Portugal and Spain, and a positive recommendation was received from NICE in the UK in December 2019.

In July 2019, Vifor Pharma concluded a licensing agreement with Otsuka Canada Pharmaceutical Inc., granting it exclusive rights to commercialise Veltassa<sup>®</sup> in Canada. Otsuka expects to launch Veltassa<sup>®</sup> in Canada in Q2 2020.

The AMBER study, a phase-II trial, was presented in May 2019 at the National Kidney Foundation Congress in Boston and published in September 2019 in The Lancet journal. Results demonstrated that Veltassa<sup>®</sup> enabled guideline-recommended use of spironolactone for blood pressure management in patients with resistant hypertension and CKD by controlling blood potassium levels. Based on the positive results of the AMBER study, Vifor Pharma decided to invest in the DIAMOND phase-IIIb outcome study to evaluate the potential of Veltassa<sup>®</sup> in combination with RAASi to improve patient outcomes, including reducing cardiovascular mortality and hospitalisations. This investment reflects our belief in the potential of expanding Veltassa<sup>®</sup> usage in this field. The first patient was enrolled in May 2019.

## **3. 2020 FINANCIAL GUIDANCE**

### **Financial guidance**

In 2020 at constant exchange rates, Vifor Pharma net sales\* are expected to grow in the range of 10%, reported EBITDA is expected to grow by more than 25%.

For further details, please see the Vifor Pharma Group 2019 Full Year Report (PDF) at [www.viforpharma.com](http://www.viforpharma.com).

### **Live conference call and webcast**

Vifor Pharma will host a live conference call (see phone numbers below) and webcast (<https://stream.swisscom.ch/vifor/20200312>) on the 12<sup>th</sup> of March 2020 at 2:00 p.m. (CET). The pin code for the live conference call is 7893117.

### Phone numbers for the live conference call

Country	Number
Switzerland	+41 31 580 0059
France	+33 17 670 0794
Germany	+49 302 215 31802
United Kingdom	+44 207 192 8000
United States of America	+1 631-510-7495
Other countries	+44 207 192 8000

### Replay

A webcast replay (<https://stream.swisscom.ch/vifor/20200312>) will be available shortly after the end of the live conference.

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**Vifor Pharma Group** is a global specialty pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is the partner of choice for pharmaceuticals and innovative patient-focused solutions. Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The company develops, manufactures and markets pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma; Vifor Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care); and OM Pharma. Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348). For more information, please visit [viforpharma.com](http://viforpharma.com).

\*Including OM Pharma.